

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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COMPLETE IF KNOWN

Sheet	1	of	6	Application Number	10/010,345
				Filing Date	December 5, 2001
				First Named Inventor	A.G. Daifotis
				Group Art Unit	1617
				Examiner Name	T.J. Criares
				Attorney Docket Number	20002YIBCA

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code (if known)		
M		5,270,365		Gertz et al.	12/14/1993
		5,366,962		Strein	11/22/1994
		4,761,406		Flora et al.	08/02/1988
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		5,994,329		Daifotis et al.	11/30/1999

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		Office	Number	Kind Code (if known)	
M			WO 95/30421		11/16/1995
			WO 96/17616		06/13/1996
			WO 94/00129		01/06/1994
			WO 94/00130		01/06/1994
			WO 94/21242		09/29/1994
			WO 95/28145		10/26/1995
			EP 0 600 834 A1		08/06/1994
			EP 0 274 158		07/13/1988
			WO 95/08331		03/30/1995
			WO 95/28936		11/02/199

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First Named Inventor	A.G. Daifotis
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Group Art Unit	1617
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Examiner Name	T.J. Criares
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Attorney Docket Number	20002YIBCA
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OTHER NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
<i>W</i>	AA	Lunar News, April 1997, "Update: Bisphosphonate", pp. 30-32
	AB	Gertz et al., Osteoporosis Int. (1993), Suppl. 3: S13-16, "Clinical pharmacology of alendronate sodium"
	AC	Gertz et al., Clin. Pharma. Ther. (1995), Vol. 58, pp. 288-98, "Studies of the oral bioavailability of alendronate"
	AD	de Vernejoul et al., Calcified Tissue Int'l, Vol. 40 (1987), pp. 160-165, "Different schedules of administration of (3 amino-1-hydroxypropylidene)-1,1-bisphosphonate induce different changes ..."
	AE	Lufkin et al., Osteoporosis Int'l. (1994), Vol. 4, pp. 320-322, "Pamidronate: An unrecognized problem in gastrointestinal tolerability".
	AF	De Groen et al., N. England J. of Medicine, (1996), Vol. 335, pp. 1016-1021, "Esophagitis associated with the use of alendronate"
	AG	Castell, (an editorial), N. England J. of Medicine (1996), Vol. 335, pp. 1058-1059, "Pill esophagitis - the case of alendronate".
	AH	Lieberman et al., (correspondence), N. England J. of Medicine (1996), Vol. 335, pp. 1069-1070, "Esophagitis and alendronate".
	AI	Chesnut et al., Am. J. of Medicine, Vol. 99 (1995), pp. 144-152, "Alendronate treatment of the postmenopausal osteoporotic woman ...".
	AJ	Cassidy et al., Digestive Diseases and Sciences, Vol. 37 (1992), pp. 1206-1211, "Continuous versus intermittent acid exposure in production of esophagitis in feline model".
	AK	Mortensen et al., J. of Bone & Mineral Res., (1995) Vol. 10, suppl. 1, p. s140, "Prevention of early postmenopausal bone loss of risendronate".
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	AN	Bankhurst et al., Arthritis and Rheumatism, Vol. 38, No. 9, Suppl. 1 (1995), S359, "Three-year treatment with alendronate prevents fractures in women with postmenopausal osteoporosis".
<i>✓</i>	AO	Filipponi et al., J. of Bone & Min. Research, Vol. 10 (1995), pp. 697-703, "Cyclical clondronate is effective in preventing postmenopausal bone loss: A comparative study with transcutaneous hormone replacement therapy".

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			Examiner Name	T.J. Criares	
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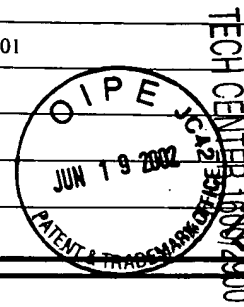
OTHER NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
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AQ		Seltenmeyer et al., Bone (NY), Vol. 20, No. 4, Suppl., (1997) pp. 114S, "A comparison of the antiresorptive potency of various bisphosphonates in vivo with their inhibitory effect in vitro on squalene synthase and cellular sterol synthesis".
AR		Adachi et al., Today's Therapeutic Trends, Vol. 14, No. 1 (1996), pp. 13-24, "Osteoporosis -- its diagnosis, management and treatment with a new oral bisphosphonate agent, etidronate".
AS		Bell et al., Endocrine, Vol. 6(2) (1997), pp. 203-206, "Bisphosphonates in the Treatment of Osteoporosis".
AT		Melsen et al., Osteoporosis, Chapt. 60(1996), pp. 1145-1158, "ADFR - The Concept and its performance".
AU		Thompson et al., J. of Bone & Min. Research, Vol. 7(1992), pp. 951-960, "The bisphosphonate, alendronate, prevents bone loss in ovariectomized baboons".
AV		Balena et al., J. Clin. Invest., Vol. 92 (1993), pp. 2577-2586, "The effects of 2-year treatment with the aminobisphosphonate alendronate on bone metabolism, bone histomorphometry, and bone strength in ovariectomized nonhuman primates".
AW		Peter et al., Digestive Diseases & Sciences, Vol. 43 (1998), pp. 1009-1015, "Comparative study of potential for bisphosphonates to damage gastric mucosa of rats".
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AY		Harris et al., J. of Clin. Endoc. & Metab., 76:1399-1406 (1993), "The effect of short term treatment with alendronate on vertebral density and biochemical markers of bone...".
AZ		Khan et al., Bone, Vol. 20 (1997), pp. 263-271, "Alendronate in the treatment of Paget's disease of bone".
BA		Physician's Desk Reference, 51st ed. (1997), pp. 1703-1706, "Fosamax".
BB		Gertz et al., J. of Bone & Min. Res., Vol. 9 (1994), pp 135-142, "Monitoring bone resorption in early postmenopausal women by an immunoassay for cross-linked collagen peptides in urine".
BC		Fleisch, J. of Clin. Endoc. & Metab., Vol. 76 (1993), pp. 1397-1398, "Editorial: Prospective use of bisphosphonates in osteoporosis".
BD		Chesnut et al., Osteoporosis Int'l (1993), Suppl. 3: S17-19, "Short-term effect of alendronate on bone mass and bone remodeling in postmenopausal women".

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		Group Art Unit	1617		
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mc	BE	Gertz et al., J. of Bone & Min. Res., Vol. 6, Suppl. 1 (1991), Abstract No. 790, p. S281, "Oral bioavailability and dose proportionality of alendronate (aminohydroxybutylidene bisphosphonate) in postmenopausal women".
	BF	Mortensen et al., J. Bone & Min. Res., (1995), 10 (Supp. 1): S360, "Prevention of early postmenopausal bone loss by residronate: A two year study".
	BG	Actonel™ (risedronate sodium tablets) package insert, dated March 1998.
	BH	Lunar News (July 1996), "Update: Bisphosphonate", pp. 23-24
	BI	Lunar News (April 1996), "Update: Bisphosphonate", p. 31
	BJ	The Pink Sheet (Dec. 18, 1995), Vol. 57, Issue 51, "Merck Cozaar generating 25,000 scripts weekly after six months on market; Foxamax off to quick start, company tells securities analyst meeting".
	BK	Scrip (11/24/99), "Merck develops once-weekly Fosamax".
	BL	Baran, Geriatrics, Vol. 56, No. 3 (March 2001), pp. 28-32, "Osteoporosis: Efficacy and safety of a bisphosphonate dosed once weekly".
	BM	Bone et al., Clinical Therapeutics, Vol. 22, No. 1 (2000), pp. 15-28, "Weekly administration of alendronate: Rationale and plan for clinical assessment".
	BN	Fleisch, Expert Opinion Therapeutic Patents, Vol. 11, No. 9 (2000), p. 1371-1381, "Bisphosphonates: mechanisms of action".
	BO	Peter et al., Journal of Pharmacology & Experimental Therapeutics, Vol. 276, No. 1 (1996), p. 271-276, "Long-term safety of the aminobisphosphonate alendronate in adult dogs".
	BP	Rodan et al., Osteoporosis International (1993) Suppl., 3:S7-12, "Preclinical Pharmacology of alendronate".
	BQ	Schnitzer, Expert Opinion Pharmacother., Vol. 2, No. 9 (2001), pp. 1461-1472, "Update on alendronate for osteoporosis: once-weekly dosing".
	BR	Schnitzer et al., Aging: Clinical and Experimental Research, Vol. 12, No. 1 (2000), P. 1-12, "Therapeutic equivalence of alendronate 70 mg once-weekly and alendronate 10 mg daily in the treatment of osteoporosis".
	BS	Seedor et al., Journal of Bone & Mineral Research, Vol. 6, No. 4 (1991), pp. 339-346, "The bisphosphonate alendronate (MK-217) inhibits bone loss due to ovariectomy in rats".

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BT		Sorrentino, Endoscopy, Vol. 28 (1996), p. 529, "Esophageal ulceration due to alendronate".
BU		Blank, American College of Gastroenterology 66th Annual Scientific Meeting, "Lack of gastric adaptation to weekly versus daily alendronate administration in rats".
BV		Bone et al., Journal of Bone & Mineral Research, Vol. 16, Suppl. 1 (September 2001), M392, "Once-weekly alendronate: Two year subgroup efficacy analyses in postmenopausal women with osteoporosis".
BW		Bone III et al., 6th International Symposium on Clinical Disorders of Bone and Mineral Metabolism, Venice, Italy, November 20-25, 1999, "Alendronate 70 mg once weekly is therapeutically equivalent to alendronate in 10 mg daily".
BX		Brown et al., Journal of Bone & Mineral Research, Vol. 16, Suppl. 1 (September 2001), M402, "Efficacy, safety and tolerability of once weekly (80 mg vs. 160 mg) oral alendronate in postmenopausal osteoporosis".
BY		Delaney et al., ENDO 2001, The Endocrine Society's 83rd Annual Meeting, Denver, Colorado (June 2001), Abstract, P1-469 (June 2001), p. 249, "Bone density changes in response to risedronate once weekly".
BZ		Gordon et al., ENDO 2001, The Endocrine Society's 83rd Annual Meeting, Denver, Colorado (June 2001), Abstract, P1-460 (June 2001), p. 247, "Weekly administration of risedronate increase bone mineral density".
CA		Lindsay et al., Arthritis & Rheumatism, Vol. 44, No. 9 (Suppl.), Abstract No. 604, "Risedronate 35 mg once a week is as effective as 5 mg daily in postmenopausal women".
CB		Rizzoli et al., Journal of Bone & Mineral Research, Vol. 16, Suppl. 1 (September 2001), M401, "Two year results of once-weekly administration of alendronate 70 mg for the treatment of postmenopausal osteoporosis".
CC		Rizzoli et al., Annals of the Rheumatic Diseases, Annual European Congress of Rheumatology, EULAR 2001, Prague, Czech Republic, Vol. 60, Suppl. 1 (July 2001), Abstract SAT0164, p. 256, "Two year results of once-weekly administration of alendronate 70 mg for the treatment of postmenopausal osteoporosis".
CD		Van Dyke, et al., Annals of the Rheumatic Diseases, Annual European Congress of Rheumatology, EULAR 2001, Prague, Czech Republic, Vol. 60, Suppl. 1 (July 2001), Abstract SAT0167, p. 256, "Safety of once-weekly alendronate 70 mg in periodontal disease".
CE		Wimalawansa, Journal of Bone & Mineral Research, Vol. 16, Suppl. 1 (September 2001), Abstract SA352, "Once a week alendronate therapy: A convenient and effective way of prevention and treatment of osteoporosis: A four-year clinical study".
CF		Wimalawansa, Journal of Bone & Mineral Research, Vol. 16, Suppl. 1 (September 2001), Abstract SU399, "Efficacy of once a week risedronate in comparison with once-weekly alendronate therapy for postmenopausal osteoporosis: One-year data".
CG		Wimalawansa, ENDO 2001, The Endocrine Society's 83rd Annual Meeting, Denver, Colorado (June 2001), Abstract P1-438, p. 241-242, "Highly efficacious and cost-effective alendronate regimen for postmenopausal osteoporosis: A four-year clinical study"
CH		Woodson, Osteoporosis International, Vol. 11, Suppl. 2 (2000), Chicago, Illinois, p. S204, Abstract 550 (514), "Once weekly risedronate therapy".

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